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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,964	11/21/2000	Michael E. O'Donnell	22221/1030 (RU-339 CIP)	2211

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Applicati n N .

09/716,964

Applicant(s)

O'DONNELL ET AL.

Examin r

Richard G Hutson

Art Unit

1652

--The MAILING DATE of this c mmunication appears on the c ver sheet with th correspondence address --

THE REPLY FILED 07 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 8 and 9.

Claim(s) rejected: 1,7,49-52,55,71-76.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

  
Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit: 1652

Continuation of 2. NOTE: Applicants proposed amendment of the claims which recites "wherein the encoded delta subunit is capable of forming a clamp loader with a delta prime subunit and a tau subunit" would require further consideration and/or search. Further, applicant proposed amendment of claim 74, limits claim 74 to a genus not yet previously searched and /or considered. It is acknowledged that applicants have previously had claims which recited many of the limitations of proposed claim 74, however it is the combination of these limitations that is not proper afterfinal. The amendment of claim 74 changing the percent identity from 75 to 90% identity to SEQ ID NO: 157, in combination with the specifically defined function of the delta subunit of a DNA polymerase III-type enzyme, in combination with the removal of the "Thermus" limitation results in the proposed after-final amendment changing the genus now being claimed. As this genus has not previously been claimed it would necessitate further consideration and/or search.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants proposed amendment of claim 1 and 73 if entered would overcome the previous 112 second paragraph rejection, however as the rejection has not been entered, the rejection remains. Further applicants attention is drawn to page 30, lines 15-17, which recites "...comprising 0.9 M sodium citrate ("SSC") buffer...", as this should be amended given applicants arguments presented on page 8 of this amendment regarding the concentration of "1X SSC" It would appear that applicants specification disagrees with the concentration of "sodium" in "SSC", whether it be 1X or 5X..

Applicants traversal of the previous 112 first paragraph rejection is in part based on applicants proposed amendment, which applicants are reminded has not been entered. Applicants further argue that the level of experimentation necessary to practice (make and use) the claimed invention does not rise to the level of "undue experimentation".

Applicants argument is not found persuasive because while the specification teaches the complete nucleotide and amino acid sequences of the delta subunit having the amino acid sequence of SEQ ID NO:158, and protocols for using the DNA of SEQ ID NO:157 as a probe, and protocols for testing for enzymatic activity, thermostability, and pH optima and methods for producing variants of a disclosed sequence are within the skill of the ordinary artisan, as well as methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants (i.e., encoding delta subunit) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. Applicants reference to WO 01/73052 does not provide the missing guidance to enable how to make and use the currently claimed isolated DNA molecules.